Remarks

Claims 1-4, 7, 8 and 20-23 are pending after entry of the amendments set forth herein. Claims 2 and 3 are withdrawn. Claims 5, 6 and 9-19 are canceled without prejudice. Claim 23 is amended to replace "a polymorphisms" with "nucleic acid sequences". Support for this amendment is found in the specification, for example, on page 14, lines 31-33 and in claim 1.

No new matter is added.

REJECTIONS UNDER §112, ¶1

Claim Rejections- 35 U.S.C. 112- New Matter

Claim 23 has been rejected as the recitation of "probes that specifically binds under stringent hybridization conditions to polymorphisms in exon 3 of TIM-1 gene" is allegedly not supported in the specification.

Without any intention to acquiesce to the correctness of this rejection and solely to expedite the prosecution of this application, claim 23 is amended to state a method of screening for a human individual's predisposition to atopy by analyzing the individual for the presence of at least one TIM-1 polymorphism in exon 3 by using probes that specifically bind to nucleic acid sequences in exon 3 of TIM-1 gene. Applicants note that claim 23 mirrors the language of claim 1.

The Office states that "[t]he specification does not contemplate the use of probes for detection of multiple polymorphisms within exon 3 of TIM-1 gene other than the four polymorphisms disclosed in the specification". Applicants submit that probes for detection of the four polymorphisms disclosed in the specification are exemplary. The specification discloses methods for detecting polymorphisms in genes (page 14, paragraph 56), for detecting polymorphisms in TIM-1 gene (page 57, paragraph 202), and methods for designing probes for detecting polymorphisms (page 15, paragraph 59). Thus contrary to the assertion in the Office Action, the specification does contemplate the use of probes for detection of multiple polymorphisms within exon 3 of TIM-1.

Applicants submit that this rejection is adequately addressed and may be withdrawn.

Claim Rejections- 35 U.S.C. 112- Enablement

Claims 1, 4, 7-8 and 20-23 are rejected under 35 U.S.C. 112, first paragraph. Specifically, the Office Action reasserts that while the specification is enabling for a method for determining a Caucasian's predisposition to atopy protection by detecting the presence of the homozygous polymorphism of 157insMTTTVP of TIM-1 in a hepatitis virus A positive Caucasian individual, wherein the presence of the MTTTVP insertion is indicative of a Caucasian's predisposition to be protected

against atopy, it is not enabling for a method for screening for a human individual's predisposition to any atopy by analyzing for the presence of any TIM-1 polymorphism.

Independent Claim 1 states a method of screening for a human individual's predisposition to atopy by analyzing the individual for the presence of at least one TIM-1 polymorphism by contacting a biological sample comprising DNA or mRNA from the individual with probes that specifically bind under stringent conditions to nucleic acid sequences of a TIM-1 gene, where the presence of the polymorphism is indicative of an individual's predisposition to develop atopy. Claim 4 refers to a probe that specifically binds to the nucleic acid of SEQ ID No: 22. Claim 8 specifically refers to detection of the INS57 polymorphism and HAV seropositivity. Claim 20 specifically refers to detection of the INS157 polymorphism, and Claim 23 to detection of polymorphisms in exon 3.

The law regarding enablement of inventions is clear: "[t]he test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."[1]

In their response to Final Office Action (Response to Final Office Action, dated October 31, 2007), the Applicants presented an evaluation of the relevant Wands factors to show how the specification clearly enables one of skill in the art to practice the claimed invention without undue experimentation in view. In response, the Office states has reiterated the rejection put forward in the last Office Action and contends that the data presented in the working examples is not statistically significant (Office Action March 3, 2008, page 21).

The Applicants submit that the statistical analysis of Applicant's data presented in the working examples of the instant application and the conclusions of the statistical analysis was published in a premier peer reviewed journal, Nature (exhibit A), where before being selected for publication, the data and the conclusions were examined by experts in the field. The Applicants submit that they have proven the validity of their statistical analysis by publishing the same data being challenged by the Office in the esteemed journal.

As per the other points raised by the Office regarding scope of the claims and the teaching in the specification, the Applicants submit that all the arguments presented in the last response apply with equal force and these arguments are not reiterated here to avoid repetition.

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[1] *United States v. Telectronics, Inc.*, 8 USPQ 2d 1217, 1233 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1046 (1989). See also *Genentech, Inc. v. Novo Nordisk*, 42 USPQ 2d 1001 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997); *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ 2d 1001 (Fed. Cir. 1991).

Claim Rejections- 35 U.S.C. 112- Written Description

Claims 1, 4, 7 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The Applicants submit that they have unambiguously proven the link between TIM-1 and atopy (see working examples). The sequence of TIM-1 and related genes in the TIM family is provided in the specification (see sequence listing). A description of common polymorphisms in TIM-1 and the linkage of TIM-1 locus to development of atopy can be found in the specification on e.g., Page 8, paragraph 37-43; page 13, paragraph 51; page 46, paragraph 169-175. Methods for detecting polymorphisms in a gene (page 14, paragraph 56) and methods for performing statistical analysis to assess whether a polymorphism in TIM-1 is linked to atopy is described in the specification (see Materials and methods, page 57, paragraphs 201-204).

While there may be sequences within the genus defined by "TIM-1 polymorphism" which will not significantly associate with atopy, the courts have clearly taught that even in unpredictable arts the specification does not have to disclose every species of a genus that would work and every species that would not work. The court has very clearly explained[2]:

> "To require such a complete disclosure would apparently necessitate a patent application or applications with thousands of catalysts....More importantly, such a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area since the patent claims would have to be limited to those embodiments which are expressly disclosed. A potential infringer could readily avoid literal infringement of such claims by merely finding another analogous catalyst complex which could be used ...."

The claims of the instant application encompass a method of screening for a human individual's predisposition to atopy which includes analyzing the individual for the presence of at least one TIM-1 polymorphism by contacting a biological sample including DNA or mRNA from the individual with probes that specifically bind under stringent conditions to the nucleic acid sequences of TIM-1, where the presence of the polymorphism is indicative of an individual's predisposition to develop atopy. Since one of skill in the art would recognize that a reasonable correlation between atopy and members of this genus is readily established by the disclosure of the instant application, and since every species in a genus does not have to be tested for the genus to be enabled, extensive, per-sequence disclosure or guidance regarding the active species in the genus does not have to be provided in order for a genus of this scope to be enabled.

As such, the specification provides adequate written description of claimed methods. Accordingly, this rejection should be withdrawn.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-235CIP.

Respectfully submitted,
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Date: August 5, 2008

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[2] *In re Angstadt*, 190 USPQ 214, at 219 (CCPA 1976)